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Effectiveness of Cognitive, Exposure, and Skills Group Manualized Treatments in OIF/OEF Female Veterans

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14. ABSTRACT
The purpose of the study is to evaluate and establish the effectiveness of three behavioral treatments for PTSD – exposure, cognitive, and skills (assertiveness/relaxation) therapies—provided in a group format. Active recruitment and treatment began February 2009. A total of 97 study subjects completed the initial assessment and 86 were randomized to either the minimal attention wait-list arm or the treatment arm. In year five, no adverse events occurred. Subject enrollment was closed on 9/1/2012 and all assessments and treatments completed on 4/5/2013, just prior to the end of year 5. The study remains open for data analysis.

15. SUBJECT TERMS- PTSD, Treatment, Female Veterans, OIF/OEF

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INTRODUCTION

The purpose of the study is to evaluate and establish the effectiveness of three behavioral treatments for PTSD--exposure, cognitive, and skills (assertiveness/relaxation) therapies--provided in a group format. The efficacies of both exposure and cognitive therapies have been well established for PTSD when provided individually and superior to other PTSD treatments. However, the robust effects have not been demonstrated when these therapies are provided in a group format. The scope of the study is to conduct this Randomized Controlled Trial examining a 16-week manualized group treatment approach in a sample of OIF/OEF female PTSD Veterans. The intent is to establish the efficacy of the 16-week treatment in three treatment blocks, and in particular exposure therapy, in a group format to inform the clinical application of these treatments for the systematic use in outpatient clinics.

BODY

The research accomplishments of the study correspond to the Statement of Work timeline and milestones.

I. YEAR 1 SUMMARY:

A. Timeline #1 (months 1-6): 1) Obtain approval by the Research and Development Committee at the NMVAHCS and Institutional Review Board at the University of New Mexico; and 2) hire the psychologist and psychology technician and train both in primary assigned duties (psychology technician to conduct assessments and psychologist in group treatment).

1) IRB Approvals: Approval by the NMVAHCS R&D and UNM IRB committees were obtained by June 7, 2008. Review by the DOD IRB was conducted and completed with approval on December 7, 2008.

2a) Staffing: The Psychologist was hired on July 7, 2008. The Psychology Technician was split into two half time positions and each was filled on 6/10/08 and 6/23/08. Additional funding ($68,750) was provided by the DOD to collect pre/post neuropsychological pilot data to assess for the effects of treatment on Traumatic Brain Injury. The funding was to cover two years of a half-time neuropsychology technician position, and testing materials. The Neuropsychology Technician was hired on 1/8/09.

2b) Training: The initial training of the Psychology Technicians was completed in September, 2008, however they could not practice on trainee subjects until DOD IRB approval of December, 2008, which began and was completed by January 30, 2009. The training of the Neuropsychology Technician was completed February 28, 2009.

It was anticipated the IRB approvals, hiring, and training would be completed in six months, but due to delay in approval by DOD IRB, the study was 4 months behind.

B. Timeline #2 (months 6 through end of year 3): Recruit participants, conduct assessments, and run study subjects through both arms of the study. Recruitment began once DOD IRB approval was confirmed in December, 2008 and has consisted of printing and distributing brochures to clinics throughout the Albuquerque VA Hospital, Albuquerque and Santa Fe Vet centers, and other VA organizations within study approval. Data from entry assessments is presently being entered into the data base stored on the VA network computers

protected by password. To date, 7 study subjects have been assessed and randomized in groups of three. The first two groups were randomized to the treatment arm, with the first group having completed 3 of the 16 sessions and the second group having completed 1 of the 16 sessions. The next three subjects will be randomized to the 16-week wait-list arm. All group sessions are being videotape recorded and are being reviewed for fidelity purposes.

C. Timeline #3 (month 9 through year 3.8): Data to be entered, statistical programs developed, data analysis begun, and completed. Meetings with the statistician have been conducted to set up the data base for data entry. Data entry has begun and is ongoing. Data analysis has not begun. Data analysis of clinic outcome data is ongoing and manuscripts are being prepared.

D. Timeline #4 (month 6 through year 4): Present at the International Society of Traumatic Stress Studies, beginning with protocol presentation in year 1, preliminary results in year 2 and 3, and final results in year 4. A workshop on the study structure was presented at ISTSS in November 2008. The study will also be presented at the VISN18 Research Forum in Phoenix in April, 2009 and at the Kansas City DOD conference in 2009.

E. Timeline #5 (year 3.8 through year 4): Manuscript write-up. This final timeline is not within review.

II. YEAR 2 SUMMARY:

A. Timeline #1 (months 1-6): Complete. Regarding staffing, the first Study Coordinator/Staff Psychologist left the study on 12/4/09, working one day/week to complete a treatment group and train the new Study Coordinator; the new Study Coordinator position was filled on 8/4/09. The new Study Coordinator is functioning successfully.

B. Timeline #2 (months 6 through end of year 3): Recruit participants, conduct assessments, and run study subjects through both arms of the study.

1. Recruitment: Recruitment is conducted by the PI and study staff (psychologist and assessment technicians) for all subjects in several forms: a) Ongoing contact with other VA staff within Behavioral Health and Medical clinics at the NMVAHCS, with the staff's invitation/consent; b) Flyers and brochures are placed in clinics throughout the hospital at the NMVAHCS, placed into packets for new patients, distributed within local community (e.g., UNM and CNM campuses), and postings are on the approved URLs (e.g., VA internet website, UNM HSC Clinical Trials website, Albuquerque's Craigslist website, and local "Alibi" on-line magazine); c) Informational meetings are periodically held at the vet centers (e.g., Albuquerque and Santa Fe); d) Advertisements will continue to be posted on the local newspaper as well as other local veteran's organization groups; e) Lastly, "Dear Patient" form letters are mailed to patients from their primary care providers/clinicians with information about the study and contact numbers. Patients are contacted through their primary care providers or if they contact the study staff.

2. Assessments: a) Treatment Arm: Five out of 18 subjects in the treatment arm have completed post, 3-, and 6-month assessments and the remaining are expected to complete follow-up assessments. b) Waitlist Arm: Three out of 6 wait-list participants have completed the pre/post

wait-list assessments and the remaining are expected to complete follow-up assessments. c) Participants Not Randomized: Two participants did not meet criteria for study; one other participant withdrew after discovering she was randomized to the wait-list arm.

3. Study Participation: a) Treatment Arm: Eight out of 18 enrolled subjects have finished the actual treatment portion of the treatment arm and have either completed or are in some phase of follow-up. Another eight enrolled subjects are currently receiving treatment. Two participants have voluntarily withdrawn from the treatment arm. b) Waitlist Arm: Three out of 7 enrolled subjects have completed the waitlist arm. Two enrolled subjects are currently in the waitlist arm. Two participants have voluntarily withdrawn from wait-list arm. c) Projected vs Actual Enrollment Numbers: The original timeline projected 18 treatment arm and 18 wait-list arm subjects (total=36) to be enrolled by the end of Year 2, an 18-month recruitment period. However, due to randomization, the adjusted projected numbers are 21 and 15 for the treatment and waitlist arms, respectively. Presently 18, treatment arm subjects have been enrolled (86% of goal) and 7 waitlist arm subjects have been enrolled (47% of goal) for an overall enrollment rate of 69%. While the percentage appears low, the actual numbers (3 for treatment and 8 for waitlist arm) are relatively small for a total of only 11 subjects. The study is becoming established and referrals have recently increased, therefore the deficit is expected to be compensated for in Year 3, as evidenced by the enrollment figures for the last quarter (5 of 6 for 83% rate). Given the 4-month delay in study commencement due to the requirement of a DoD IRB review, the study is progressing as expected.

C. Timeline #3 (months 9 through year 3.8): Timeline #3 includes data entry, developing statistical programs, and initial/final data analysis.

1. Data Entry: Data has begun and is ongoing for initial and follow-up assessments. Fidelity checks are conducted at regular intervals with data checks for accuracy.

2. Statistical Analyses: The statistician has regular meetings with the PI and Study Coordinator and statistical analyses have begun and are ongoing with regular data checks. Final analyses are not under this review.

D. Timeline #4 (months 6 through year 4): Presentation of preliminary and outcome data at conferences and develop manuscripts.

1. Presentations at Conferences: No presentations were conducted during Year 2, however, during Year 2, three abstracts with preliminary results were submitted to the International Society of Traumatic Stress Studies (ISTSS) conference for presentation in November, 2010 in Quebec, Canada. Abstracts are presently under review.

2. Manuscripts: Final manuscript preparation is not under review in Year 2. Manuscripts on clinic general psychiatric and outcome data in Military Sexual Trauma (MST) females was submitted and rejected; it will be revised and resubmitted to another journal. A second manuscript on specific group outcome data of exposure therapy was

submitted and rejected; manuscript will be revised and resubmitted to another journal.

E. Timeline #5 (year 3.8 through year 4): Write manuscript(s) and submit for publication. This final timeline is not within review.

III. YEAR 3 SUMMARY:

A. Timeline #1 (months 1-6): **Completed**. Staffing Updates: The Study Coordinator position was upgraded to account for the additional clinical and administrative responsibilities assigned to the position. The ½ time Assessment Technician position has remained unfilled and a new study psychologist position was created to conduct fidelity/reliability checks on assessments and treatment group sessions, as well as assist with the clinical duties (co-leading exposure group sessions, providing wait-list supportive individual sessions) and with data analysis and managing the data base. The funding of the new psychologist position will be taken from the vacant ½ time technician position and the monies budgeted for the consultant at the Boston VA who was originally slated to conduct reliability/fidelity checks.

B. Timeline #2 (months 6 through end of year 3–adjusted to end of year 4.25): Recruit participants, conduct assessments, and run study subjects through both arms of the study.

1. Recruitment: Recruitment is conducted by the PI and study staff (psychologist and assessment technicians) for all subjects in several forms: a) Ongoing contact with other VA staff within Behavioral Health and Medical clinics at the NMVAHCS, with the staff's invitation/consent; b) Flyers and brochures are placed in clinics throughout the hospital at the NMVAHCS, placed into packets for new patients, distributed within local community (e.g., UNM and CNM campuses), and postings are on the approved URLs (e.g., VA internet website, UNM HSC Clinical Trials website, Albuquerque's Craigslist website, and local "Alibi" on-line magazine); c) Informational meetings are periodically held at the vet centers (e.g., Albuquerque and Santa Fe); d) Advertisements will continue to be posted on the local newspaper as well as other local veteran's organization groups; e) Lastly, "Dear Patient" form letters are mailed to patients from their primary care providers/clinicians with information about the study and contact numbers. Patients are contacted through their primary care providers or if they contact the study staff.

2. Assessments: a) Initial Intake Assessments: 26 new initial assessments were conducted. 5 were randomized to the Treatment arm, 10 to the wait list arm, 7 from wait list to treatment, 2 drop outs, and 2 excluded. Treatment Arm Assessments (post, 3-, and 6-month): A total of 30 assessments were conducted with subjects in the treatment arm (*Note:* this number does not reflect each subject, but rather represents duplicate and triplicate for some subjects). b) Waitlist Arm: 12 wait-list participants completed the post wait-list assessment.

3. Study Participation: a) Treatment Arm: Total number of subjects in the treatment arm for Year 3 was 20 (*Note:* this includes carry-over from Year 2, those who completed treatment and all follow-up assessments, and those still active). Four participants voluntarily

withdrew from the treatment arm. b) Waitlist Arm: A total of 17 subjects participated in the waitlist arm of the study in Year 3(*Note:* this includes those who completed waitlist, follow-up assessment, and those still active). Two participants voluntarily withdrew from wait-list arm.

4. Projected vs Actual Enrollment Numbers: For the first three years of the study, enrollment has been at 80% of the targeted number (See Table 1 and Figure 1 for actual versus projected enrollment). The projected number of subjects to be enrolled and completed by end of Year 3, was 60, but is actually 48. It was expected the deficits would be compensated for in later years, however the actual enrollment has averaged 4.8 subjects per quarter versus the expected enrollment of 6 per quarter. At this rate, the study will not complete enrollment by the end of the 4th year and a one-year extension will be necessary to obtain the targeted number of subjects (N=72; see Table 2).

C. Timeline #3 (months 9 through year 3.8–adjusted to end of year 5): Timeline #3 includes data entry, developing statistical programs, and initial/final data analysis.

1. Data Entry: Data entry continues for initial and follow-up assessments. Fidelity checks for data entry are regularly conducted for data accuracy.

2. Statistical Analyses: The PI and Study Coordinator continue to meet weekly with the statistician. Statistical programs have been and continue to be written and data analyses have begun with regular data checks. Final analyses are not under this review.

D. Timeline #4 (months 6 through year 4–adjusted to end of year 5): Presentation of preliminary and outcome data at conferences and develop manuscripts.

1. Presentations at Conferences: Three abstracts with preliminary results were presented (1 paper and 2 posters) in Year 3 at the International Society of Traumatic Stress Studies (ISTSS) conference in November, 2010 in Quebec, Canada. Two additional abstracts were submitted to the upcoming ISTSS conference in November, 2011, in Washington, DC, and are under review.

2. Manuscripts/Grant Submission: Final manuscript preparation is not under review in Year 3, but has begun. Manuscripts from other studies are being revised and resubmitted to scientific journals. A grant was submitted in December, 2010 to VA HSR&D extending and further developing the methodology of the present study, but it was not funded. The grant application will be revised and resubmitted in May 2011. A second grant application is in development and will be submitted to DoD in May 2011, extending the study to male OIF/OEF veterans.

E. Timeline #5 (year 3.8 through year 4): Write manuscript(s) and submit for publication. This final timeline is not within this review period, however manuscript for main outcome results is in preparation.

IV. YEAR 4 SUMMARY:

A. Timeline #1 (months 1-6): **Completed**.

B. Timeline #2 (months 6 through end of year 3—adjusted to end of year 5): Recruit participants, conduct assessments, and run study subjects through both arms of the study.

1. Recruitment (No change from year 3 summary): Recruitment is conducted by the PI and study staff (psychologist and assessment technicians) for all subjects in several forms: a) Ongoing contact with other VA staff within Behavioral Health and Medical clinics at the NMVAHCS, with the staff's invitation/consent; b) Flyers and brochures are placed in clinics throughout the hospital at the NMVAHCS, placed into packets for new patients, distributed within local community (e.g., UNM and CNM campuses), and postings are on the approved URLs (e.g., VA internet website, UNM HSC Clinical Trials website, Albuquerque's Craigslist website, and local "Alibi" on-line magazine); c) Informational meetings are periodically held at the vet centers (e.g., Albuquerque and Santa Fe); d) Advertisements will continue to be posted on the local newspaper as well as other local veteran's organization groups; e) Lastly, "Dear Patient" form letters are mailed to patients from their primary care providers/clinicians with information about the study and contact numbers. Patients are contacted through their primary care providers or if they contact the study staff.

2. Assessments:

a) Initial Intake Assessments: 40 new initial assessments were conducted. 18 were randomized to the Treatment arm, 16 to the wait list arm, 7 from wait list to treatment, 2 drop outs, and 4 excluded.

b) Treatment Arm Assessments (post, 3-, and 6-month): A total of 98 post, 3-, and 6-month assessments were conducted on subjects in the treatment arm (*Note:* this number does not reflect each subject, but rather represents duplicate and triplicate for some subjects).

c) Waitlist Arm Assessments: 25 wait-list participants completed the post wait-list assessment.

3. Study Participation:

a) Treatment Arm: Total number of subjects in the treatment arm for Year 4 was 30 (*Note:* this includes carry-over from Year 3, treatment completers, and active from both Treatment arm and Waitlist to Treatment subjects). Two participants voluntarily withdrew from the treatment arm and two participants were withdrawn.

b) Waitlist Arm: A total of 13 subjects participated in the waitlist arm of the study in Year 4(*Note:* this includes those who completed waitlist, follow-up assessment, and active). Three participants voluntarily withdrew and one participant was withdrawn from wait-list arm.

4. Projected Enrollment Numbers: Initial projections for the study were 36 randomized to treatment and 36 to waitlist arms (n=72) with carryover of 36 from waitlist to treatment for a total of 72 in the treatment arm and 36 in the waitlist arm (N=108). Based on Year 4 calculations and adjustments for excludes/drop outs, 18 more subjects will be required (Treatment=9, Waitlist=9) to complete the study. Enrollment will continue until August 2012.

C. Timeline #3 (months 9 through year 3.8—adjusted to be completed at end of year 5): Timeline #3 includes data entry, developing statistical programs, and initial/final data analysis.

1. Data Entry: Data entry continues for initial and follow-up assessments. Fidelity checks for data entry are regularly conducted for data accuracy.

2. Statistical Analyses: The PI and Study Coordinator continue to meet weekly with the statistician. Statistical programs have been and continue to be written and data analyses have begun with regular data checks. Final analyses are not under this review.

D. Timeline #4 (months 6 through year 4—adjusted to the end of year 5): Presentation of preliminary and outcome data at conferences and develop manuscripts.

1. Presentations at Conferences: One poster containing preliminary results was presented in Year 4 at the International Society of Traumatic Stress Studies (ISTSS) conference in November, 2011 in Baltimore, MD. One workshop was presented in March 2012 at the Institute on Violence, Abuse, and Trauma (IVAT) in Honolulu, HI.

2. Manuscripts/Grant Submission: Final manuscript preparation has begun. Manuscripts from other studies are being revised and resubmitted to scientific journals. Two grants are in preparation for submission to DoD and VA CSR&D in 2012.

V. YEAR 5 SUMMARY: Timeline #5 No Cost Extension (year 4 through year 5):

A. Timeline #1 (months 1-6): **Completed**.

B. Timeline #2 (months 6 through end of year 5): Recruit participants, conduct assessments, and run study subjects through both arms of the study.

1. Recruitment (through 9/1/12—No change from year 3 summary): Recruitment was conducted by the PI and study staff (psychologist and assessment technicians) for all subjects in several forms: a) Ongoing contact with other VA staff within Behavioral Health and Medical clinics at the NMVAHCS, with the staff's invitation/consent; b) Flyers and brochures are placed in clinics throughout the hospital at the NMVAHCS, placed into packets for new patients, distributed within local community (e.g., UNM and CNM campuses), and postings are on the approved URLs (e.g., VA internet website, UNM HSC Clinical Trials website, Albuquerque's Craigslist website, and local "Alibi" on-line magazine); c) Informational meetings are periodically held at the vet centers (e.g., Albuquerque and Santa Fe); d) Advertisements will continue to be posted on the local newspaper as well as other local veteran's organization groups; e) Lastly, "Dear Patient" form letters are mailed to patients from their primary care providers/clinicians with information about the study and contact numbers. Patients are contacted through their primary care providers or if they contact the study staff.

2. Assessments:

a) Initial Intake Assessments: 10 new initial assessments were conducted. 3 were randomized to the Treatment arm, 5 to the wait list arm, 0from wait list to treatment, 2 drop outs, and 0 excluded.

b) Treatment Arm Assessments (post, 3-, and 6-month): A total of 41 post, 3-, and 6-month assessments were conducted on subjects in the treatment arm (*Note:* this number does not reflect each subject, but rather represents duplicate and triplicate for some subjects).

c) Waitlist Arm Assessments: 6 wait-list participants completed the post wait-list assessment.

3. Study Participation:

a) Treatment Arm: Total number of subjects in the treatment arm for Year 5 was 25 (*Note:* this includes carry-over from Year 4, treatment completers, and active from both Treatment arm and Waitlist to Treatment subjects). 6 participants voluntarily withdrew from the treatment arm.

b) Waitlist Arm: A total of 7 subjects participated in the waitlist arm of the study in Year 5(*Note:* this includes those who completed waitlist, follow-up assessment, and active). One participant voluntarily withdrew.

4. Final Enrollment Numbers: Initial projections for the study were 36 randomized to treatment and 36 to waitlist arms (n=72) with carryover of 36 from waitlist to treatment and oversampling for a total of 72 in the treatment arm and 36 in the waitlist arm (N=108). Final figures resulted in 97 total subjects enrolled, with 86 meeting eligibility requirements; with 44 randomized to the treatment arm, 42 to the Waitlist arm, and of the latter, 25 requesting treatment.

C. Timeline #3 (months 9 through end of year 5): Timeline #3 includes data entry, developing statistical programs, and initial/final data analysis.

1. Data Entry: Data entry continued for initial and follow-up assessments. Fidelity checks for data entry are regularly conducted for data accuracy.

2. Statistical Analyses: The PI continues to meet weekly with the statistician. Statistical programs have been and continue to be written and data analyses have begun with regular data checks. Final analyses are not under this review.

D. Timeline #4 (months 6 through year 5): Presentation of preliminary and outcome data at conferences and develop manuscripts.

1. Presentations at Conferences: One paper was presented at the American Psychological Association in August, 2012 in Orlando, FL on the neuropsychological findings.

2. Manuscripts/Grant Submission: Final manuscript preparation has begun. Manuscripts from other studies are being revised and resubmitted to scientific journals. Three grants were submitted to DoD (2, one with Dr. C'de Baca as PI)and VA (1) CSR&D in 2013 to further investigate group exposure therapy.

Manuscript writing has begun.

KEY RESEARCH ACCOMPLISHMENTS

I. YEAR 1:

1) Overall successful commencement of research project
2) Hiring and Training of Study Staff
3) Collaboration with Boston Consultants
4) Completed IRB approvals
5) Weekly staff meetings
6) Training materials (videotapes, cds) created
7) Ongoing monitoring of patient safety
8) Expansion of project to add neuropsychological component and staff
9) Successful initiation of recruitment and running of subjects
10) Successful interface with statistician for set up of data base

II. YEAR 2:

1) Completed IRB Reapprovals and Amendments
2) Ongoing weekly research staff meetings to monitor study progress
3) Ongoing recruitment and enrollment of study subjects
4) Ongoing monitoring of patient safety in weekly in staff meetings and annually with independent Medical Monitor
5) Ongoing consultation and collaboration with Boston Consultants
6) Hiring/Training of new Study Coordinator
8) Successful interface with statistician for creating statistical programs and conducting preliminary analyses
9) Successful submissions of abstracts to ISTSS conference for presentation of significant positive results based on initial analyses

III. YEAR 3:

1) Completed. IRB Reapprovals and Amendments are current.
2) Weekly research staff meetings to monitor study progress continue.
3) Recruitment and enrollment of study subjects continues.
4) Patient safety is monitored in weekly in staff meetings and annually with independent Medical Monitor—ongoing.
5) Consultation and collaboration with Boston Consultants—ongoing.
6) Hiring/Training of new study psychologist.
8) Weekly meetings with statistician (creating statistical programs and conducting preliminary analyses)—ongoing.
9) Successful presentations of data at ISTSS conference (2010) showing significant positive outcome results in initial analyses.
10) Submission of abstracts to ISTSS conference (2011) on significant positive longitudinal outcome results from treatment--pending. Total submissions to ISTSS = 4 (includes other non-DoD data).
11) Submission of two new Randomized Control Trials extending this study (one grant compares PE to CPT in group format in male OIF/OEF veterans; second compares PE to PCT in group format in female veterans).

IV. YEAR 4:

1) IRB Reapprovals and Amendments are current.
2) Weekly research staff meetings to monitor study progress continue.
3) Recruitment and enrollment of study subjects continues.

4) Patient safety is monitored in weekly in staff meetings and annually with independent Medical Monitor—ongoing.
5) Consultation and collaboration with Boston Consultants—as needed.
7) Weekly meetings with statistician (statistical programming and conducting preliminary analyses)—ongoing.
8) Fidelity and reliability ratings on Initial and Follow Up Assessments, and on group Treatment blocks (cognitive, exposure, skills) have begun. Fifteen percent of all assessments and treatments will be evaluated for reliability and consistency with protocol.
9) Successful presentations of data at ISTSS (2011) and IVAT (2012) conferences showing significant positive outcome results in initial analyses.
10) Submission of abstracts to APA conference (2012) on significant positive longitudinal outcome results from treatment--pending.
11) Preparation of two new Randomized Control Trials extending this study (one grant compares PE to CPT in group format in male OIF/OEF veterans; second compares individual PE to group PE in female veterans).

V. YEAR 5:
1) IRB Reapprovals and Amendments are current.
2) Weekly research staff meetings to monitor study progress continue.
3) Recruitment and enrollment of study subjects continued through 9/1/2012.
4) Patient safety is monitored in weekly in staff meetings and annually with independent Medical Monitor—ongoing.
5) Consultation and collaboration with Boston Consultants—as needed.
7) Weekly meetings with statistician (statistical programming and conducting preliminary analyses)—ongoing.
8) Fidelity and reliability ratings on Initial and Follow Up Assessments, and on group Treatment blocks (cognitive, exposure, skills) have been completed. Fifteen percent of all assessments and treatments were evaluated for reliability and consistency with protocol and data entered, to be analyzed in year 6.
9) Successful presentations of data at APA (2012) conferences showing significant positive outcome results in initial analyses.
10) Submission of abstracts to ISTSS and APA conferences (2013) on final outcome results—significant positive longitudinal outcome results from treatment and on ethnicity composite of study participants.
11) Two new Randomized Control Trials extending this study (one grant compares PE to CPT in group format (C'de Baca, PI, Castillo, Co-PI) in male OIF/OEF veterans; second (submitted to DoD and VA) compares individual PE to group PE in female veterans) have been completed and submitted for review.

REPORTABLE OUTCOMES

I. YEAR 1:
1) Presentations to professional groups, including ISTSS, regional VA research conference (VISN 18 Research Forum), and National DOD research conference.
2) Although no data is yet available for analysis/presentation/write-up, manuscript writing on clinical support data continues with submission to one

journal. Manuscript was rejected, revisions are being made, and manuscript will be resubmitted to another journal.

II. YEAR 2:

1) Overall descriptive data analyses. For the current 18 subjects, descriptive data reflects a younger (Mean age=34.6 y.o.), well-educated (mean education > 14 years), ethnically diverse sample (white, non-Hispanic < 17%), with many co-morbidities (Axis I=78%, Axis II=22%).

2) Outcome Results. Preliminary analyses on the small number of subjects (n=8) in the treatment arm of the study has shown a statistically significant 20-point reduction of PTSD symptoms (pre to post treatment) on current CAPS scores (preM=58.3, postM=38.4, p<.03), the main outcome measure. Another measure of functioning (SF36) showed significant improvement on four of the eight scales from pre to post treatment. Reductions were on the physical functioning, role limitations due to emotional problems, energy/fatigue, and emotional well-being (p<.05) scales.

3) Study Events. While a small number of subjects have withdrawn from both treatment and waitlist arms of the study, the reasons identified were personal and not study-related. Testimonials from the patients completing the treatment arm have been generally positive. No serious adverse events have occurred; no increases in risk to patients have occurred. No reportable events have occurred.

III. YEAR 3:

1) Overall descriptive data analyses. Preliminary descriptive data (*n*=46) reflected a young (*M*=36), educated (91% some college), ethnically diverse (43% Hispanic, 24% Native American), highly traumatized (94%>3 trauma types; 90%>10 trauma incidents) sample, with Axis I and II co-morbidities (78% and 22%, respectively) and high total Clinician Administered PTSD Scale (CAPS) scores (*M*=156). 2) Longitudinal Outcome Results. A repeated measures analysis of pre, post, 3-, and 6-month follow-up in subjects completing all phases of treatment (*n*=10) showed significant decreases on the total (*p*=.01; *ES*=1.08), re-experiencing (*p*=.02; *ES*=0.79), and avoidance/numbing (*p*=.03; *ES*=1.1) CAPS PTSD scores (20 point decrease maintained at 6 month follow-up). Three of eight SF36 scales (role limitations due to emotional problems, emotional well-being, and social functioning, *p*<.03) also maintained significance at 6 month follow up. 3) Study Events. One study subject randomized to the waitlist arm was hospitalized for psychiatric admission twice within a 4-week period in the last 4 weeks of the 16 week wait list period. Hospitalization was not deemed study related. Withdrawals of other study subjects were also not deemed study-related. Testimonials from the patients completing the treatment arm continue to be generally positive. No increases in risk to patients have occurred.

IV. YEAR 4 (no new analyses):

1) Overall descriptive data analyses. Preliminary descriptive data (*n*=46) reflected a young (*M*=36), educated (91% some college), ethnically diverse (43% Hispanic, 24% Native American), highly traumatized (94%>3 trauma types; 90%>10 trauma incidents) sample, with Axis I and II co-morbidities (78% and

22%, respectively) and high total Clinician Administered PTSD Scale (CAPS) scores (*M*=156).
2) Longitudinal Outcome Results. A repeated measures analysis of pre, post, 3-, and 6-month follow-up in subjects completing all phases of treatment (*n*=10) showed significant decreases on the total (*p*=.01; *ES*=1.08), re-experiencing (*p*=.02; *ES*=0.79), and avoidance/numbing (*p*=.03; *ES*=1.1) CAPS PTSD scores (20 point decrease maintained at 6 month follow-up). Three of eight SF36 scales (role limitations due to emotional problems, emotional well-being, and social functioning, *p*<.03) also maintained significance at 6 month follow up.
3) Study Events. One study subject randomized to the waitlist arm was psychiatrically hospitalized for medication overdose after one month of study participation. Hospitalization was not deemed study related. Determination of withdrawal from study was based on noncompliance in the treatment arm. Testimonials from the study subjects completing the treatment arm continue to be positive. No increases in risk to patients have occurred.

V. YEAR (analyses ongoing):
1) Overall descriptive data analyses. Descriptive data (*n*=86) reflected a young (*M*=36), educated (89% some college), ethnically diverse (40% Hispanic, 17% Native American), highly traumatized (96%>3 trauma types; 92%>10 trauma incidents) sample, with Axis I and II co-morbidities (78% and 22%, respectively) and high total Clinician Administered PTSD Scale (CAPS) scores (*M*=154).
2) Outcome comparison between two arms. An ANOVA comparing pre/post CAPS scores in both study arms (Tx vs. WL) found a significant interaction ($p < .001$) and a significant main effect for the Treatment arm with pre/post CAPS scores decreasing 23 points to below clinic cutoff for the PTSD diagnosis. Secondary analyses are ongoing and will be fully reported in the final report.
3) Longitudinal Outcome Results. A repeated measures analysis of pre, post, 3-, and 6-month follow-up in subjects completing all phases of treatment (*n*=32) showed significant decreases on the total CAPS PTSD scores ($p < .001$; *ES*=1.08), (decreases maintained at 6 month follow-up).
3) Study Events. No events occurred in this period. Testimonials from the study subjects completing the treatment arm have been positive. No increases in risk to patients have occurred.

CONCLUSION

YEAR 1:
The only problem the study faced was in start up in the wait for DOD IRB review and approval, which delayed commencement of the study. The result was a four-month delay. Despite this delay and once approved, the study began quickly and has experienced no other problems. Data collection and entry is going smoothly, regular meetings are held within the study staff, with the statistician, and with Boston consultants to assure fidelity of administration of interview instruments.

YEAR 2:

The second year of the study showed a successful follow up to the implementation of the study after the first year. Study enrollment is slightly behind the projected numbers, however recent enrollment figures suggest the numbers will be made up in year 3. Some study staff have changed, but new staff have quickly picked up the pace. The main outcome measure for group treatment effectiveness is statistically significant with reductions in PTSD symptoms shown with only 8 subjects. Testimonials suggest the treatment is well-tolerated and results show positive effects. The study's positive progress is supported by the independent Medical Monitor. The study staff are active in analyzing data and submitting presentation proposals to international conferences.

YEAR 3:

The third year of the study has shown continued success in entry, randomization, treatment (or waitlist), and follow up assessments. Study enrollment continues to be slightly behind the projected numbers, however enrollment has been steady. It is anticipated that a no-cost extension will be submitted 6 months prior to the end of the study in order to obtain all the data necessary for a fully powered analysis. Study staffing has remained stable and the new staff member will be able to help the study meet goals of completing fidelity and reliability monitoring. The main outcome longitudinal analysis for group treatment effectiveness is statistically significant with reductions in PTSD symptoms maintained 6 months after treatment in 10 subjects thus far. Testimonials suggest the treatment is well-tolerated and results show positive effects. The study's positive progress is supported by the independent Medical Monitor. The data analysis and conference submission is ongoing and grant funding is progressing to replicate and extend positive results.

YEAR 4:

The fourth year of the study continues to show success in entry, randomization, treatment (or waitlist), and follow up assessments. Study enrollment continues to be slightly behind the projected numbers, with some slow, but mostly steady periods. The primary problem facing study completion is the extended time required (10 month total) for participation in the Treatment Arm (Treatment=4 months, follow up assessments=6 months). It was determined that the last date of enrollment is August 1, 2012. As such, follow up assessments will still need to be conducted after January 1, 2013 and as late as June, 2013, which is past the 5th year of the study. In consultation with the grant manager, it was agreed that a 2nd no cost extension will be requested to complete assessments, data analysis and manuscript preparation. The 2nd no-cost extension will be submitted 6 months prior to the end of the study. Study staffing has remained stable and fidelity and reliability monitoring has begun. The main outcome longitudinal analysis for group treatment effectiveness is statistically significant with reductions in PTSD symptoms maintained 6 months after treatment in 21 subjects thus far. Testimonials suggest the treatment is well-tolerated and results show positive effects. The study's positive progress is supported by the independent Medical Monitor. The data analysis and conference submission

is ongoing and grant funding is progressing to replicate and extend positive results.

YEAR 5:

The fifth year of the study has shown success in entry, randomization, treatment (or waitlist), and follow up assessments. Enrollment was closed on September 1, 2012. Staffing was reduced with the exit of the Study Coordinator in September, 2012 and the two half time Technicians at the end of December, 2012. The treatments were completed in December, 2012 and the last of the follow up assessments were completed the first week of April, one week after the end of the 5th year. A 2nd no cost extension was granted for a full 6th year, however data entry has been completed and data analysis and manuscript preparation are anticipated to be completed by the end of June 2013. The main outcome longitudinal analysis for group treatment effectiveness is statistically significant with reductions in PTSD symptoms maintained 6 months after treatment. The main outcome manuscript will be submitted to the Journal of Consulting and Clinical Psychology. Two additional manuscripts are in the planning for analyses on ethnic baseline and demographic characteristics and cultural response to exposure therapy. Two oral presentations have been accepted by the APA for August, 2013 and one has been submitted to ISTSS for November, 2013. Subject testimonials suggest the treatment is well-tolerated and results show positive effects. The study's positive progress is supported by the independent Medical Monitor. It is anticipated further grant funding will extend the -programming of research comparing a stand-alone group exposure model.

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APPENDICES

YEAR 3:
APPENDIX A-1

A Randomized Controlled Trial for Group Exposure, Cognitive, and Skills Therapies in Female OEF/OIF Veterans

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Abstract
Group delivery of exposure and cognitive therapies has not demonstrated the comparable robust effects the individual literature has shown in PTSD improvement (Cahill, et. al., 2009). A Randomized Controlled Trial (RCT) examined a 16-week group delivery of exposure, cognitive, and skills treatment blocks in female Iraq/Afghanistan veterans with PTSD. Preliminary descriptive data (*n*=46) reflected a young (*M*=36), educated (91% some college), ethnically diverse (43% Hispanic, 24% Native American), highly traumatized (94%>3 trauma types; 90%>10 trauma incidents) sample, with Axis I and II co-morbidities (78% and 22%, respectively) and high total Clinician Administered PTSD Scale (CAPS) scores (*M*=156). A repeated measures analysis of pre, post, 3-, and 6-month follow-up in subjects completing treatment (*n*=10) showed significant decreases on the total (*p*=.01; *ES*=1.08), re-experiencing (*p*=.02; *ES*=0.79), and avoidance/numbing (*p*=.03; *ES*=1.1) CAPS scores. Additionally, significant improvement was found on three of eight SF36 scales (role limitations due to emotional problems, emotional well-being, and social functioning, *p*<.03). Initial comparisons on the PTSD Symptom Checklist (PCL; *n*=22) between blocks of treatment (cognitive, exposure, skills) showed significant PTSD decreases in the skills group block; data will be analyzed controlling for block order effects. Detailed descriptive data and outcome analyses with implications will be presented.

Learning Objectives & Keywords (Complete):

***Learning Objective 1**: Participants will be able to identify the outcome measures which including those for PTSD that improve with group therapy for female veterans.

***Learning Objective 2**: Participants will be able to identify the three group components included in the 16-week manualized group treatment for PTSD in female veterans.

***Learning Objective 3**: Participants will be able to identify 3 characteristics of the sample of OEF/OIF female veterans treated with manualized group treatment.

***Program type:**
Clinical/intervention research

***Population type:**
Military/peacekeepers/veterans

YEAR 3:
APPENDIX A-2

PTSD Treatment impacts PTSD Symptoms but not Neuropsychological Performance in Female OIF/OEF Veterans with PTSD: Preliminary Findings

Sullivan, Elizabeth A., Ph.D.[1] , Keller, Jenna, BS [1], Chee, Christine, Ph.D. [1], Castillo, Diane, Ph.D. [1], Haaland, Kathleen, Ph.D. [1,2]
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Abstract:
A growing body of literature suggests impaired neuropsychological performance in individuals with PTSD. Although research has increasingly demonstrated the efficacy of treatment for PTSD in improving psychological symptoms, comparatively little is known about the impact of PTSD treatment on neuropsychological functioning. The few studies that have attempted to examine this issue have largely focused on male veterans, whereas the growing population of female veterans makes examining these issues in a female veteran sample of current significance. The current study assessed neuropsychological performance before and after group treatment in a sample of 16 female OIF/OEF veterans with PTSD compared to 15 non-veteran healthy controls. Results indicate that before treatment the PTSD group demonstrated lower IQ and decreased neurocognitive performance in comparison to the control group. Following treatment, the PTSD group demonstrated significant decreases in their PTSD symptoms, but continued to evidence decreased neuropsychological performance in comparison to the control group. There were no significant group by treatment interactions, suggesting that the PTSD groups' neuropsychological performance did not change any more than the control group. Subsequent analyses examine the ability of PTSD symptoms to predict neurocognitive functioning independently of IQ, and the degree that post-treatment symptom reduction predicts post-treatment neuropsychological performance.

Learning Objectives & Keywords:
Learning Objective 1: Participants will become familiar with common neuropsychological sequelae of PTSD.
Learning Objective 2: Participants will become familiar with frequent methodological concerns in conducting treatment outcome research.
Learning Objective 3: Participants will gain increased understanding of how PTSD symptoms can impact attention and memory.
Keywords: Neuropsychological performance, PTSD, Treatment change, Veterans, Female, OIF/OEF

YEAR 3:
APPENDIX A-3

Group Exposure Therapy for PTSD in Female Veterans

Symposium paper (1 of 3)
Diane T. Castillo, Ph.D.

Design and results for a model of group exposure therapy conducted in small (*n* =3) groups with female veterans will be provided from clinic data, a randomized control trial (RCT), and a proposal for an independent 10-session model. Outpatient clinical data from 21 groups demonstrated improvement in total (p = .008; *ES* = 0.36), re-experiencing (p = .05; *ES* = 0.28), and avoidance/numbing (p = .0004; *ES* = 0.59) Post-traumatic Stress Disorder (PTSD) Symptom Checklist (PCL) scores in a 6-week group within a larger program of other structured group interventions (e.g., cognitive). Similarly, improvement in total (p = .01; *ES* = 1.08), re-experiencing (p = .02; *ES* = 0.79), and avoidance/numbing (p = .03; *ES* = 1.1) Clinician Administered PTSD Scale (CAPS) scores were found in a 16-week group RCT, which included a 5-session exposure block, a finding maintained at 3- and 6-month follow-up. The safety and efficacy of group exposure established by the clinical and RCT data led to the development of a 10-session group exposure therapy model, which solely utilizes exposure therapy, similar to the Prolonged Exposure individual protocol, and will be described as the next phase in group exposure therapy with female veterans.

YEAR 3:
APPENDIX A-4

Personality patterns of non-Hispanic White, African American, and Hispanic women veterans diagnosed with PTSD

Janet C'de Baca, Diane Castillo, Clifford Qualls
New Mexico VA Health Care System

ABSTRACT
Prevalence rates in the United States of any Personality Disorder are 9.1% (Lenzenweger, Lane, & Kessler, 2007). Personality Disorders are inflexible patterns of perceiving, reacting, and relating to people and events, impairing the ability to function socially (American Psychiatric Association, 1994). A growing literature indicates personality pathology may be higher in those experiencing trauma and diagnosed with posttraumatic stress disorder (PTSD; Ghafoori & Hierholzer, 2010; Daud, Klinteberg, & Rydelius, 2007; Dunn et al., 2004; Yen et al., 2002). Among traumatic events, rape and combat exposure pose the highest risk for development of PTSD (Kessler et al., 1995; Wolfe et al, 1998; Fontana, Litz, & Rosenheck, 2000). Racial and ethnic differences in personality pathology in this population (women veterans) is less understood (Ghafoori & Hierholzer, 2010). Understanding cultural differences in the expression of symptoms is important to treatment planning. The study population is comprised of 398 women veterans diagnosed with PTSD based on the Clinician Administered PTSD Scale, and who completed the Millon Clinical Multiaxial Inventory-III. Thirty-four percent met criteria for a Cluster A Personality Disorder (PD), 19% for Cluster B PD, and 43% for Cluster C PD. We will examine ethnic differences in Personality Disorders among female veterans in treatment for PTSD.

YEAR 3:

APPENDIX B-1

Manualized Group Delivery of Exposure Therapy in Female Veterans. Submitted to HSR&D, merit review, PI—Castillo

APPENDIX B-2

Effectiveness of Manualized Cognitive and Exposure Group Treatments in OIF/OEF Male Veterans. In preparation For submission to DoD. Co-PI—C'de Baca and Castillo.

YEAR 2:
APPENDIX C-1

Title: Effectiveness of Cognitive, Exposure, and Skills Group Manualized Treatments in OIF/OEF Female Veterans- Preliminary Findings

Authors: Diane T. Castillo, Ph.D., Christine Chee, Ph.D.

Abstract: Exposure and cognitive therapies have demonstrated the largest effect sizes in treating PTSD (Rothbaum, et. al., 2000) with the delivery of protocols predominantly evaluated in an individual format. While group delivery of treatments has been the format of choice in VA outpatient PTSD clinics, the research is equivocal. A unique group format offering systematic exposure and cognitive therapies is being examined in an ongoing Department of Defense funded study in female OIF/OEF veterans with PTSD. Methodology consists of an assessment, randomization to a structured 16-week group (three blocks: exposure, cognitive, skills) or waitlist arm, and post-assessment with 3- and 6-month follow up assessment in treatment subjects. Preliminary analyses on 18 subjects reflect a younger, well-educated, ethnically diverse sample, with co-morbidities (Axis I=78%, Axis II=22%), and total mean CAPS scores of 155. A most interesting finding in the small (n=8) treatment subsample was a significant 20-point reduction of PTSD symptoms on current CAPS scores (pre$M$=58.3, post$M$=38.4, p<.03) and improvement on four SF36 scales (physical functioning, role limitations due to emotional problems, energy/fatigue, emotional well-being, p<.05). No differences between types of treatment were found on the PCL. Detailed analysis on profile presentation and outcome data, with implications will be presented.

Key Words: Clinical or Intervention Research; Culture/Diversity

YEAR 2:
APPENDIX C-2

Title: Development of an Emotional Stroop Task for OIF/OEF Female Veterans: Preliminary Findings

Authors: Rinehart, J., Keller, J., Leiphart, S., Castillo, D., and Haaland, K.Y.

Abstract: PTSD is associated with automatic biases in selective attention. The emotional Stroop task has been used to measure this bias in male combat veterans and female sexual assault victims. No research has investigated female veterans who have PTSD associated with combat and/or sexual trauma. In order to construct a valid Stroop task for this group, neutral, social anxiety, combat, and sexual trauma words were obtained from previous studies (e.g. Foa et al., 1991; McNally et al., 2000) and generated by therapists treating female veterans with PTSD. The therapists rated 90 combat and sexual trauma words for emotional salience, and the ten most salient words in each category were selected for the current task. The emotional salience ratings of female veterans with PTSD and a demographically-matched healthy control group were compared. Preliminary data suggests that neutral words were rated similarly (p = .750), but combat words (t = 3.50, p <.01), sexual trauma words (t = 2.74, p <.05), and social anxiety words (t = 2.16, p =.045) were rated as more emotionally upsetting by the PTSD group. These results support the face validity of this Stroop task to assess attentional biases associated with PTSD due to combat and sexual trauma.

Key words: PTSD, OIF/OEF veterans, emotional Stroop, female veterans

YEAR 2:
APPENDIX C-3

Title: Neuropsychological Deficits in Female Veterans with PTSD: Preliminary Findings

Authors: Keller, J., Rinehart, J., Leiphart, S., Chee, C., J., and Haaland, K.Y.

Abstract: Neuropsychological deficits, especially in attention, executive functions, and memory, are commonly associated with combat-related PTSD in male veterans. This ongoing DOD-funded study investigated neuropsychological functioning in female veterans with combat and/or sexual trauma to determine if a similar pattern of deficits was seen. We assessed estimates of general intelligence (Wechsler Test of Adult Reading), attention/working memory (Working Memory Index, WAIS-III), executive functions (Composite measure from the Delis-Kaplan Executive Function System), memory (California Verbal Learning Test), and processing speed (WAIS-III Index) in 13 female veterans with PTSD and 12 demographically-matched healthy control participants. One patient was excluded from each group for possible compromised effort (Test of Memory and Malingering). The PTSD group's performance was within the average range but poorer ($p<.05$) than the control group across all measures, except memory. These preliminary findings are consistent with findings in male veterans except for the lack of memory impairment, which is likely due to the small sample size and low power. Results will be discussed in terms of potential preexisting vulnerabilities, neurobiological effects of PTSD, and the influence of behaviors associated with PTSD (e.g., depression) that may affect neuropsychological performance.

Presentation Preference: Paper

Key Words: PTSD; Neuropsychological assessment; neurocognitive deficits, OIF/OEF veterans; depression; combat trauma; sexual trauma

YEAR 2:

APPENDIX D--DRAFT OF MANUSCRIPT GENERAL OUTCOME CLINICAL DATA

Running head: MST CHARACTERISTICS AND TREATMENT

Characteristics of Female Veterans with Military Sexual Trauma and Effectiveness of Group-Based Cognitive-Behavioral Interventions

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Key words: trauma, women, MST, treatment, PTSD

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Abstract

Characterization of female veterans with military sexual trauma (MST) has been limited to psychological and medical co-morbidities and treatment studies have not targeted this population. We provide descriptive data (demographics, psychological testing, and PTSD) in a clinical sample of female veterans with MST. Eighty-nine percent reported MST, with 93% sexual traumas, 55% both childhood and adult traumas, and 88% more than one trauma, suggesting a population at risk for developing PTSD. Testing patterns reflect a sample with anxiety, depression, and PTSD. Outcomes on cognitive, exposure, and behavioral group interventions demonstrate the effectiveness of group delivery of evidence-based treatments for PTSD.

Characteristics of Female Veterans with Military Sexual Trauma and Effectiveness of Group-Based Cognitive-Behavioral Interventions

Military Sexual Trauma (MST) is defined by the Veterans Administration (VA) broadly to include both events of sexual assault and sexual harassment found to occur during active military service, whether by another service person or by a civilian. The importance of identifying the incidence and presentation of MST in all veterans is gaining attention both in active duty and veteran populations, particularly in females (Valente & Wight, 2007), due to the increased risk of psychological and physical sequelae. Suris and Lind (2008) found that female veterans experiencing MST were at a higher risk for the psychiatric problems of depression, alcoholism, and Posttraumatic Stress Disorder (PTSD), along with higher risk of chronic health problems. Kimerling, Gima, Smith, Street, and Frayne (2007) found higher co-morbidities of PTSD and medical diagnoses among MST survivors. Himmelfarb, Yaeger and Mintz (2006) found that women with MST were more likely to develop PTSD than with other types of trauma and Yaeger, Himmelfarb, and Mintz, (2006) reported MST significantly predicted PTSD in their sample of female veterans. Kimerling, Street, Gima, and Smith, (2008) reported increased mental health utilization among male and female veterans reporting MST with the universal screening tool in Veterans Administration hospitals. In a recent sample of female veterans returning from the Iraq and Afghanistan wars, Katz, Bloor, Cojucar, and Draper (2007) reported a high incidence of MST in their sample. The data on both older and younger female veterans suggests military sexual trauma is an ongoing problem that has significant negative implications for psychiatric and medical consequences. The first aim of the present study is to provide more detailed descriptive information on female veterans with MST and PTSD. Descriptive demographic data, including trauma details, along with PTSD severity using the Clinician Administered PTSD Scale (CAPS; Blake, Weathers, Nagy, Kaloupek, Klauminzer, Charney, & Keane 1990), and psychological test results will be provided.

While information about MST has focused on the prediction of psychiatric and medical consequences of the experience, little exists on psychological presentation and even less on evidence-based treatments of the psychological symptoms, specifically PTSD in individuals with MST. One

treatment study (Rauch, Defever, Favorite, Duroe, Garrity, Martis, & Liberzon, 2009) examined Prolonged Exposure (PE) with a variety of veterans with trauma, some of which included female veterans with MST. These authors found significant improvement with the PE treatment overall. Schnurr, Friedman, Engel, Foa, Shea, Chow, et al. (2007) conducted the first systematic application of PE in a large sample of female veterans with PTSD, many of whom had MST and found significant improvement in PTSD symptoms. While the individual treatment literature has consistently demonstrated the largest effect sizes in reduction of PTSD symptoms (Cahill, Rothbaum, Resick, & Follette, 2009) occur with both PE therapy (Foa, Dancu, Hembree, Jaycox, Meadows, & Street, (1999a; Foa, Dancu, Hembree, Jaycox, Meadows, & Street, 1999b) and cognitive restructuring (Resick, Jordon, Girelli, Hutter, & Marhoefer-Dvorak, 1988) with neither displaying superiority over the other nor a cumulative effect when the two treatments are combined (Resick, Nishith, Weaver, Astin, & Feuer, 2002; Marks, Lovell, Noshirvani, Livanou, & Thrasher, 1998), historically treatments in VA populations have occurred in a group format (Garrick, 2000). However, the literature on group administration of treatment protocols has not shown the same differential findings as the individual literature. The group literature has been plagued with methodological flaws, but in general the three types of groups consist of supportive, psychodynamic, and cognitive-behavioral approaches, all found equally effective in treating PTSD (Shea, McDevitt-Murphy, Ready, & Schnurr, 2009). The most recent comparison of treatment type in a group format where PE was compared to present-centered therapy in male combat veterans found improvement in both, but failed to find significant differences between groups (Schnurr, Friedman, Foy, Shea, Hsieh, Lavori, et al., 2003).

The second aim of this study is to present clinical data on the effectiveness of systematic outpatient group protocols in an applied setting in female MST veterans diagnosed with PTSD. A unique PTSD group treatment format (Castillo, 2004) was developed and implemented at the New Mexico VA Health Care System (NMVAHCS) in 1995. This treatment format minimally alters the researched treatment protocols for PTSD, yet provides timely interventions and accounts for patient choice in treatment options. A brief description of the interventions and outcome analyses are presented on a sample of female veterans with MST attending treatment.

Method

Participants

Participants initially included 379 female veterans evaluated for treatment and meeting criteria for current and/or lifetime PTSD in an outpatient PTSD clinic between 1995 and 2009. Medical record review revealed 89% (n = 338) reported Military Sexual Trauma (MST), therefore 41 were eliminated from analyses. MST was documented through mandated clinical survey for all veterans seeking medical/psychological treatment at Veterans Administration hospitals and was defined as either sexual harassment and/or sexual assault which occurred during active duty service. The mean age of the study sample was 43.8 (SD = 10.4). Trauma details are provided in Table 1, with 51% reporting sexual trauma only, and an additional 43 % sexual trauma with another type of trauma. Age at time of trauma consisted of 37% adulthood, 56% both adult and childhood trauma, and 7% childhood. Eighty-eight percent reported more than one trauma and 13% were exposed to combat. The breakdown among branches of the service is 46% Army, 27% Air Force, 19% Navy, 6% Marine Corps, 1% Coast Guard, and 1% Reserves/National Guard. Sixty-four percent were diagnosed with PTSD and another psychiatric diagnosis. Sixty percent were non-Hispanic white, 26% Hispanic, and 14% other ethnicities. Twenty-nine percent were married, 42% divorced, 25% never married, and 4% widowed.

Assessment

Entry into the clinic consisted of a clinical semi-structured interview, computer administration of a battery of psychological tests, and interview administration of the Clinician Administered PTSD Scale (CAPS; et al., 1990). The CAPS included the 17-symptom portion to assess for frequency and intensity of the PTSD symptoms within the past month and lifetime. The psychological tests included the Minnesota Multiphasic Personality Inventory-2 (MMPI2; Butcher, 1989), the Millon Clinical Multiaxial Inventory II and III (MCMI-II; Millon, 1987; (MCMI-III; Millon, 1994; Millon, Davis, & Millon, 1997), the Beck Depression Inventory, original and second version (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961; BDI2; Beck, Steer, & Brown, 1996), and the Buss-Durkee Hostility Inventory (BDHI; Buss & Durkee, 1957). The MMPI2 is a self-report personality inventory consisting of 567 true-false items, with

validity, Clinical, Content, Supplementary, Restructured and Psy5 scales. The MCMI-II/ III is a 175 item, true-false, self-report questionnaire, which contains scales for general psychiatric conditions found on Axis I, as well as Axis II personality disorders based on the DSM-IV. The MCMI consists of Base Rate (BR) scores for Modifier Indices, Clinical Syndrome, Personality Disorder Syndrome scales. The BDI/BDI2 is a 21-item, Likert scale which contains four options for each item, each scored from 0-3, and assesses for depression within the past week. The administration of different versions of the BDI and MCMI were due to changes/updates in clinic assessment procedures. The BDHI is a 75-item, true-false measure that has been used both clinically and in research and includes eight anger scales, three cognitive (Resentment, Suspicion, and Guilt) and five behavioral (Assault, Indirect Hostility, Irritability, Negativism, and Verbal Hostility).

Assessment Profiles. Table 2 shows the Current, Lifetime, and Total CAPS scores, BDI/BDI2, and BDHI scores, with comparable CAPS scores to other populations (Gray, Litz, Hsu, & Lombardo, 2004), BDI scores in the severely depressed range, clinically significant elevations on the two BDHI cognitive anger scales, Resentment and Suspicion. Table 3 contains the MMPI2 Clinical scales, Supplementary, Content, Psy5, and RC scales. Our sample had *t* - score peaks above 80 on the F, Depression, and Schizophrenia scales, similar to male combat veterans with PTSD (Munley, Bains, Bloem, & Busby, 1995). On the Supplementary and Content Scales, the highest score was on Keane's PTSD scale; while two Anxiety scales, the Depression, Health Related Concerns, Work Concerns, and Negative Treatment Indicator scales had scores greater than 70. There were clinically significant elevations (> 70) on the Demoralization, Somatic Complaints, Low Positive Emotion of the Restructured Clinical scales and Introversion/Low Positive Emotion of the Psy5 scales. Table 4 displays the MCMI-II and MCMI-III scores, with about half of the sample in each and base rate scores greater than 80 on the Schizoid and Avoidant scales of the MCMI-II and Anxiety and PTSD scales of the MCMI-III.

Outcome measure. The PTSD Symptom Checklist (PCL; Weathers, Litz, Herman, Huska, & Keane, 1993), is a 17-item six-point Likert scale with each PTSD symptom anchored from 0 (not at all) to

5 (extremely). The PCL was administered in the first and last group session of the four structured PTSD group interventions described below.

Procedure

Treatment components. The treatment program consisted of a series of structured groups (see full description in Castillo, 2004), which began with general support in the PsychEd group, followed by protocol-specific treatment in the Cognitive, Skills, Sexual Intimacy, and Exposure Groups. Group sessions were 90-minutes and met eight times, except for the Exposure Group which met six. Attendance in each group was selected by the patient with the guidance of the therapist.

Cognitive restructuring, conducted in the Cognitive Group, consisted of didactics of general cognitive restructuring (Kanfer & Schefft, 1988) followed by addressing distorted belief in the five areas from Cognitive Processing Therapy (CPT; Resick & Schnicke, 1993), but excluded the exposure component. Weekly homework writings and in-session review of the current distorted beliefs caused by the traumas were identified for the five content areas of safety, trust, power/competence, esteem, and intimacy. The writings were read aloud by the patients, challenged, and modified in each session. The Skills Group consisted of didactic and experiential assertiveness training with videotaped, in-session role-play. Five different relaxation methods were reviewed and practiced in the final 30 minutes of sessions two through six, one each week, and assigned daily, at-home practice. Nightmare therapy (Krakow et al., 2001) was conducted in the seventh session, with group review of the nightmare, modification of the content to an empowering theme, and imaginal rehearsal of the redesigned dream daily, particularly prior to sleep. The Sexual Intimacy Group was implemented to address the psychological sexual sequelae associated with rape. Readings from a reference book for general sex education (Heiman & LoPiccolo, 1988) were assigned each week. In addition to discussing the impact of the readings, cognitive restructuring and assertiveness skills were applied to sexual functioning issues. Exposure therapy consisted of a combination and modification of flooding/exposure by techniques Keane (Keane, Fairbank, Caddell, & Zimering, 1989; Keane, Fairbank, Caddell, Zimering, & Bender, 1985), Foa (Foa, Hembree, & Rothbaum , 2007), and Resick (Resick & Schnicke, 1992). After selection of the worst/index trauma,

patients were instructed to write a detailed description, read it aloud in session, and were guided through an imaginal exposure in sessions two through five for a total of four in-session guided imaginal exposures. Patients were instructed to read the narrative daily for two weeks after the third writing. The order of treatment was Cognitive followed by Skills, Sexual Intimacy, and Exposure groups. All data was collected through archival record review and approved by local Institutional Review Boards.

Results

Outcome Analyses

The PCL scores for the protocol-specific groups, Exposure, Cognitive, Skills, and Sexual Intimacy, were analyzed for Total PTSD scores and for the three symptom categories—Reexperiencing, Avoidance/Numbing, and Hyperarousal. The Exposure Group contained 20 groups with a total of 41 participants with pre/post data (8 missing post); the Cognitive Group, 37 groups with 100 participants (88 missing post); the Skills Group, 34 groups with 70 participants (57 missing post); and the Sexual Intimacy Group, 23 groups with 57 participants (45 missing post). The number of participants in the Exposure Groups was limited to three and ranged from 4-10 in the other groups. Before combining data across groups, an analysis of variance (ANOVA) was computed on baseline PCL scores within the group types to assure equality of groups. As no significant differences were found between groups in any of the four group types, the individual data was combined for analyses within each group type. Next, computations within each group type were conducted to assure the validity of the pre/post data and to address missing data (due to drop outs, failure to administer the PCL). An ANOVA and *t* – tests were computed on baseline PCL scores between those with and without post PCL scores. No significant differences were found in any of the four group types in either analysis. A more conservative logistic regression analysis was computed to determine if post PCL scores were predicted by baseline scores. Analyses within all four group types resulted in non-significant findings, suggesting that the post test scores were missing at random.

Paired *t* - tests (see Table 5) were computed for individuals with both pre and post PCL scale scores within each group type. Significant improvement in Total PTSD symptoms was found in the

Exposure ($p < .005$), Cognitive ($p < .0001$), and Skills ($p < .001$) group treatments and the effect sizes were moderate to low (range = 0.3-0.5). The largest effect size for change (0.5) was in the Exposure group. In the Reexperiencing and Avoidance/Numbing PTSD subcategories, the Exposure ($p < .05$, $p < .001$, respectively), Cognitive ($p < .005$, $p < .0001$, respectively), and Skills ($p < .01$, $p < .05$, respectively) group treatments showed significant decreases. The largest effect size was 0.6 in the Avoidance/Numbing symptom category with the Exposure group. In the Hyperarousal PTSD symptom category, the Cognitive ($p < .0001$) and Skills ($p < .005$) groups showed significant results with smaller effect sizes. The Sexual Intimacy Group produced no significant improvement in PTSD symptoms.

Discussion

The results from the present study contribute to our knowledge about MST in female veterans by adding detailed descriptive information about the population and by providing information on effectiveness of evidence-based treatments in a group format. It is important to note that over 89% of female veterans seeking PTSD treatment in an outpatient women's PTSD clinic reported experiencing MST and of those exposed to MST, 40% experienced additional other traumas along with sexual traumas, resulting in 94% with sexual and other traumas. Therefore, only a minority of female veterans entering psychiatric treatment will not have experienced sexual trauma, speaking to the importance of establishing safe waiting environments and gender specific providers. Other trauma characteristics, such as the large number reporting both childhood and adult trauma (56%) and diagnosed with more than PTSD alone (88%), support previous findings that female veterans with MST will likely have multiple psychological problems and are at risk for medical and psychiatric health consequences (Suris & Lind, 2008; Kimerling et al., 2007; Himmelfarb et al., 2006; Kimerling et al., 2008).

The assessment data characterizes a sample of female veterans with high levels of current PTSD and even higher rates at another time in their lifetimes. Depression scores are at severe levels and anger scores are predominantly in internal, cognitive representations, such as feeling

mistreated (Resentment) and mistrusting others (Suspicion), much like their male counterparts with PTSD (Castillo, Fallon, C'de Baca, Conforti, & Qualls, 2002), although males also showed elevations on severe behavioral anger, such as verbal and physical aggression. While the sample's PTSD and depression scores were high, the psychological tests averaged in the valid range with elevations on depression and anxiety measures and Axis II elevations on scales reflecting avoidance of people and preference for isolation (Schizoid and Avoidant) on the MCMI. The findings are important, as the presentation of female veterans with MST begins to take shape. The extremes of psychopathology were not found: severe psychopathology, such as psychoticism or bipolar patterns were not present, nor were character disorders, such as borderline, narcissistic, histrionic personality disorders found. Female veterans with MST and PTSD display a pattern of testing characterized by anxiety and depression, both of which PTSD overlaps and comparable to other samples with PTSD.

A promising finding of the present study is the replication of individual protocol treatments in a group setting, demonstrating improvements in PTSD symptoms with cognitive, exposure, and other behavioral interventions (assertiveness, relaxation, and nightmare therapies) in female veterans with MST. In overall PTSD symptom reduction, the series of structured groups, except the sexual functioning group, lead to a subsequent drop in PTSD symptomatology with exposure therapy providing the largest drop, even as a last therapy in the sequence. The findings are consistent with the literature, in that both the cognitive and exposure groups had the larger effect sizes over the other general behavioral intervention, but also inconsistent in that the combination of cognitive and exposure therapies provided an additive effect (Resick et al., 2002). This is one of the first studies to demonstrate the effectiveness of exposure therapy in a group format. In a hallmark study, Schnurr et al. (2003) failed to find differences between a PE

and present centered group, although the PE protocol was radically altered. Ready et al., (2008) has recently demonstrated the effectiveness of PE imbedded in a group with other interventions, but the most common delivery method tested and found effective is an individual format (Foa et al., 2007). This is the first study to isolate exposure therapy within a small group and find it to be superior to other behavioral interventions. It is interesting to note that within the symptom categories, exposure treatment provided the largest change in both the reexperiencing and the avoidance/numbing symptoms, suggesting that exposure is a potent therapy and primarily targets these two categories. The failure to find a decrease in hyperarousal symptoms could be due to the fact that exposure was offered last in the treatment sequence. While caution should be exercised in interpreting non-significant PTSD symptom improvement in the Sexual Intimacy Group, the result has important implications. Past group research has shown that all group treatments for PTSD, regardless of intervention (Shea et al., 2009) show equally positive improvement in symptomatology, including general support groups, with no differential findings as in the individual literature. Our findings show that only certain group treatments, which include support, positively impact PTSD symptoms; however some protocols, like treatment of sexual functioning, do not improve PTSD symptoms. Thus, while some treatments for PTSD are differentially effective, not all treatments improve PTSD. The present study not only replicated the positive effects found by researched protocols in a real-world sample, but also demonstrated that improvements with structured interventions can be produced in group format.

Several limitations of this study should be noted. First, the sample of female MST veterans was treatment-seeking for PTSD, therefore the profiles are necessarily biased toward a more pathological population, in this case PTSD, and are not representative of all female veterans with MST. Secondly, MST is defined to include individuals with sexual harassment,

creating a wide range of experiences which singly might not qualify as traumatic. Our sample is narrow with regards to participants who had severe sexual harassment, sexual trauma, or other traumas that would qualify for the diagnosis of PTSD. Therefore, the results reflect female MST veterans who have PTSD. Finally, the limitations associated with clinical data are the same methodological issues that plague most group research (Shea et al., 2009), such as no randomization, no control group, quality assurance of intervention. A current clinical randomized trial (Castillo, Keane, & Montgomery, 2008, November) is in progress to assess for the effectiveness of group interventions, controlling for methodological problems.

Despite the limitations, the present study provides a baseline clinical presentation of female MST veterans with PTSD and pilot data on the group delivery of evidence-based treatments. The clinical implication is the feasibility of offering effective, time-limited, protocol-specific treatments in a group format. The data from the present sample provides a protocol for PTSD treatment in the most flexible form: group interventions for maximizing therapist time, options for patients to select from a menu of the most effective treatments for PTSD, and the availability of both cognitive and exposure therapies as options.

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Table 1

Trauma Characteristics of Female Veterans with MST

	n	%		n	%
Military Sexual Trauma	338	89	**Age at Time of Trauma***		
			Childhood	23	6.8
Type of Trauma*			Adulthood	124	36.8
Sexual	173	51.3	Both	190	56.4
Physical/Emotional	7	2.1			
Other	11	3.3	**Number of Traumas****		
Combination (sexual +)	146	43.3	One	38	11.3
			> One	298	88.7

Note. * missing = 1; **missing = 2.

Table 2

Means and Standard Deviations on CAPS, BDI, and BDHI of Female Veterans with MST

	M (*SD*)		*M* (*SD*)
CAPS (*n* = 255)		**BDHI** (*n* = 219)	
Current	74.5 (24.9)	Assault	54.0 (11.8)
Lifetime	106.8 (22.3)	Indirect Hostility	49.6 (10.3)
Total	180.0 (45.1)	Irritability	55.1 (8.7)
		Negativism	52.3 (12.6)
BDI (*n* = 146)	24.7 (11.8)	Resentment	65.7 (12.1)*
BDI2 (*n* = 148)	30.3 (12.0)	Suspicion	68.3 (13.9)*
		Verbal Hostility	50.1 (11.8)
		Guilt	53.0 (9.4)

Note. * indicates clinical significance with *t* scores greater than 60.

Table 3

Means and Standard Deviations on the MMPI2 Clinical, Select Supplementary/Content, RC, and Psy5 scale in Female Veterans with MST

MMPI2 (n = 308)	*M* (*SD*)		*M* (*SD*)		*M* (*SD*)
Clinical Scales		**Supplementary Scales**		**Content Scales**	
L (Lie)	52.0 (9.6)	Anxiety	70.8 (39.2)	Anxiety	73.5 (11.3)
F (Fake Bad)	86.9 (21.2)	Repression	55.8 (12.2)	Fears	57.9 (14.1)
K (Fake Good)	40.9 (9.0)	Ego Strength	33.6 (6.6)	Obssessiveness	63.4 (12.0)
1 (Hypochond)	74.6 (12.6)	Overcontrolled Hostility	46.5 (9.5)	Depression	72.8 (12.6)
2 (Depression)	79.6 (15.0)	Dominance	36.8 (7.9)	Health Concerns	75.0 (13.4)
3 (Hysteria)	71.3 (14.6)	PTSD Keane	79.8 (14.3)	Bizarre Mentation	65.0 (15.3)
4 (Psych Dev)	72.7 (12.7)	MacR	54.3 (13.2)	Anger	63.4 (12.4)
5 (Masc-Fem)	56.3 (10.6)			Cynicism	61.6 (11.7)
6 (Paranoia)	74.3 (16.6)	**RC Scales**		Antisocial Behav	57.2 (11.3)
7 (Psychasth)	75.2 (12.9)	RCd (Demoralization)	70.8 (10.6)	Low Self Esteem	66.8 (13.4)
8 (Schizoph)	82.3 (15.2)	RC1 (Som Complaints)	74.2 (12.4)	Social Discomfort	66.5 (12.9)
9 (Hypomania)	56.8 (11.8)	RC2 (Low Pos Emo)	73.0 (16.2)	Family Concerns	67.3 (12.2)
0 (Soc Introv)	66.0 (11.0)	RC3 (Cynicism)	62.0 (12.7)	Work Concerns	71.3 (12.9)
		RC4 (Antisocial Beh)	63.2 (11.3)		
		RC6 (Ideas of Pers)	66.2 (14.1)	**Psy5 Scales**	
		RC7 (Dysf Neg Emo)	67.8 (13.1)	Aggressiveness	53.1 (13.5)
		RC8 (Aberrant Exper)	66.1 (15.4)	Psychoticism	66.9 (15.7)

	RC9 (Hypoman Activ)	52.9 (11.1)	Disconstraint	52.3 (12.0)
			Negative Emo	67.4 (11.6)
			Introversion	72.9 (16.2)

Note. Hypochond = Hypochondriasis, Psych Dev = Psychopathic Deviate, Masc-Fem = Masculinity-Femininity, Psychasth = Psychasthenia, Schizoph = Schizophrenia; Soc Introv = Social Introversion. MacR = MacAndrews Alcoholism-Revised; Som Complaints = Somatic Complaints, Low Pos Emo = Low Positive Emotions, Antisocial Beh = Antisocial Behavior, Ideas of Pers = Ideas of Persecution, Dysf Neg Emo = Dysfunctional Negative Emotions, Aberrant Exper = Aberrant Experiences, Hypoman Activ = Hypomanic Activation; Negative Emo = Negative Emotionality/Neuroticism, Introversion = Introversion/Low Positive Emotionality.

Table 4

Means and Standard Deviations on the MCMI-II and MCMI-III in Female Veterans with MST

	MCMI-II*	**MCMI-III****		**MCMI-II**	**MCMI-III**
	M (*SD*)	*M* (*SD*)		*M* (*SD*)	*M* (*SD*)
Modifying Indices			**Severe Personality Pattern**		
X Disclosure	68.2 (18.6)	72.9 (16.0)	Schizotypal	71.3 (22.4)	64.4 (17.3)
Y Desirability	50.0 (18.1)	41.7 (18.1)	Borderline	67.6 (21.4)	64.2 (22.8)
Z Debasement	70.0 (22.0)	76.4 (13.1)	Paranoid	65.2 (18.3)	67.7 (20.9)
Clinical Personality Pattern					
Schizoid	80.3 (23.1)	78.0 (16.0)	**Clinical Syndromes**		
Avoidant	84.6 (20.1)	74.6 (19.7)	Anxiety	71.3 (26.3)	84.2 (17.8)
Depressive		72.5 (21.2)	Somatoform	64.9 (15.7)	69.9 (22.8)
Dependent	61.5 (33.1)	63.5 (25.5)	Bipolar: Manic	46.0 (21.7)	54.5 (23.7)
Histrionic	51.6 (28.3)	28.1 (22.6)	Dysthymic	74.8 (28.3)	71.9 (24.4)
Narcissistic	55.5 (29.2)	41.8 (22.2)	Alcohol Dependence	54.9 (19.7)	54.4 (22.5)
Antisocial	66.7 (19.4)	53.8 (21.0)	Drug Dependence	54.9 (20.1)	52.5 (23.7)
Aggressive/Sadistic	62.7 (25.2)	57.8 (17.6)	PTSD		79.9 (15.0)
Compulsive	65.4 (20.7)	50.8 (20.3)			
Negativistic		65.6 (20.7)	**Severe Clinical Syndromes**		
Passive/Aggressive	72.0 (30.5)		Thought Disorder	63.4 (18.4)	61.2 (19.5)
Masoschistic		71.1 (23.8)	Major Depression	69.8 (21.3)	76.1 (24.7)

Self-Defeating	75.9 (21.8)	Delusional Disorder	55.8 (18.2)	45.9 (32.2)

Note. * $n = 139$; ** $n = 146$.

Table 5

Paired *t* - test for Total PTSD Symptom Checklist (PCL) Scores and PCL Scores by Symptom Category for Each Treatment Group

			PTSD Symptom Categories					
	PCL Total		Reexperiencing		Avoidance/ Numbing		Hyperarousal	
Group	*M (SD)*	ES	*M (SD)*	ES	*M (SD)*	ES	*M (SD)*	ES
Cognitive (*n* = 100)								
Pre	64.5 (12.1)		18.7 (4.3)		26.1 (5.7)		19.7 (4.0)	
Post	59.3[e] (15.5)	0.4	17.4[c] (5.1)	0.3	23.6[e] (6.9)	0.4	18.3[d] (4.8)	0.4
Skills (*n* = 70)								
Pre	62.3 (13.2)		18.4 (4.4)		24.9 (6.3)		19.0 (4.1)	
Post	58.4[d] (12.9)	0.3	17.3[b] (4.5)	0.3	23.5[a] (6.1)	0.2	17.7[c] (4.1)	0.3
Sexual Intimacy (*n* = 57)								
Pre	58.6 (16.3)		17.6 (5.2)		23.4 (7.0)		17.6 (5.3)	
Post	56.4 (15.6)		16.8 (5.2)		22.8 (6.7)		16.8 (4.9)	
Exposure (*n* = 41)								
Pre	60.4 (13.4)		17.6 (4.5)		24.6 (6.6)		18.2 (4.2)	
Post	53.5[c] (17.0)	0.5	15.7[a] (5.8)	0.4	20.5[d] (7.2)	0.6	17.3 (5.5)	

Note. PCL = PTSD Symptom Checklist; *M* = mean; *SD* = standard deviation; ES = Effect Size; [a] $p < .05$, [b] $p < .01$, [c] $p < .005$, [d] $p < .001$, [e] $p < .0001$.

YEAR 1:
APPENDIX E

Title: Effectiveness of Cognitive, Exposure, and Skills Group Manualized Treatments in OIF/OEF Female Veterans

Authors: Diane T. Castillo, Terry Keane, Catherine Montgomery

Abstract: The purpose of this workshop is to present a group protocol treatment for PTSD from a recently funded study and will detail how effective therapy interventions—exposure, cognitive, and behavioral—can be provided in structured, small groups. Therapies found most effective for PTSD are exposure and cognitive, with less support for other treatments (Rothbaum, et. al., 2000). Studies have been conducted individually, while most PTSD treatments in VA hospitals are conducted in groups (Garrick, 2000). The literature has shown no difference between specific interventions in groups, including exposure in a group format (Schnurr, et. al., 2003), while support for group exposure was found in a clinical setting (Castillo, 2004). METHODOLOGY: Assessment: pre, post, 3-, and 6-month post treatment; between treatment blocks. Procedure: 72 female OIF/OEF veterans positive for PTSD randomized into a three-person, 16-week treatment group or wait-list control. Blocks: Exposure: trauma and safety nets identified; imaginal exposure. Cognitive: didactic cognitive restructuring, writing of beliefs on safety, trust, power/competence, and esteem/intimacy, distortions examined in session. Behavioral: didactic and videotaped role-play assertiveness training, 4 relaxation techniques. Attendees will gain information on the application of evidence-based treatments for PTSD in a manualized treatment group.

YEAR 1:
APPENDIX F

ABSTRACT FOR KANSAS CITY DOD RESEARCH CONFERENCE

Title: Effectiveness of Cognitive, Exposure, and Skills Group Manualized Treatments in OIF/OEF Female Veterans

Author: Diane T. Castillo

Abstract: This presentation will provide details from the DOD funded study intended to investigate a group therapy treatment protocol for PTSD in female OIF/OEF veterans. The presentation will consist of a literature review, rationale, and description of the study. The established effective therapy interventions for PTSD, exposure, cognitive, and behavioral, will be examined systematically in small, structured groups of three women. Therapies found most effective for PTSD are exposure and cognitive, with lower effect sizes for other treatments (Rothbaum, et. al., 2000). Most studies have examined the individual administration of these therapies, while most PTSD treatments in VA hospitals are conducted in groups (Garrick, 2000). In general, therapies for PTSD offered in groups have been found equally effective and specifically no differences were found between exposure therapy and present centered therapy in a group format (Schnurr, et. al., 2003). In a clinical setting (Castillo, 2004), support for group exposure was found in small structured groups. METHODOLOGY: The study assessment (SCID I/II, CAPS, LEC, others) will consist of an extensive pre, post, 3-, and 6-month follow up and the PCL will be administered between treatment blocks. After assessment, 72 female OIF/OEF veterans positive for PTSD randomized into a three-person, 16-week treatment group or wait-list/minimal attention control. The 16-weeks of treatment will consist of structured therapy in three blocks: Exposure: trauma and safety nets identified; imaginal exposure. Cognitive: didactic cognitive restructuring, writing of beliefs on safety, trust, power/competence, and esteem/intimacy, distortions examined in session. Behavioral: didactic and videotaped role-play assertiveness training, 4 relaxation techniques. Attendees will gain information on the application of evidence-based treatments for PTSD in a manualized treatment group.

YEAR 1:

APPENDIX G--DRAFT OF MANUSCRIPT FROM CLINICAL GROUP EXPOSURE DATA

Running Head: EFFECTIVENESS OF GROUP-BASED EXPOSURE

Effectiveness of Group-Based Exposure Therapy for PTSD:

A Preliminary Investigation

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Word Count: 2,246 plus 200 words (one table =100 words and one figure =100 words) = total 2,446 words

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Abstract

Exposure therapy has consistently been shown to be superior to other treatments for posttraumatic stress disorder (PTSD). However, the only systematic examination of exposure therapy conducted in a group format (Schnurr, et al., 2003) failed to show differential improvement over a present-centered approach. Exposure therapy was conducted in small, time-limited (6 weeks) groups within a larger outpatient clinical PTSD program for females in a VA setting. The results showed improvement in total PTSD scores and within the reexperiencing and avoidance/numbing symptom categories. Quadratic analyses were significant for expected increase/decrease in PTSD symptoms across sessions and order of exposure treatment was not relevant to outcome. The results support the utility of exposure therapy in small groups.

A Preliminary Investigation

Exposure therapy, a behavioral intervention for the treatment of Post-traumatic Stress Disorder (PTSD), has consistently been shown to be effective (Marks, Lovell, Noshirvani, Livanou, & Thrasher, 1998) and efficacious (Foa, Hembree, Cahill, Rauch, Riggs, Feeny, Yadin, 2005) in reducing PTSD symptoms in various populations. Initial work examining the utility of exposure therapy focused on the treatment of PTSD among civilian rape victims (Foa, Rothbaum, Riggs, & Murdock, 1991) and male combat veterans (Boudewyns, Hyer, Woods, Harrison, & McCranie, 1990). Most recently, Schnurr and colleagues (2007) found that compared to present-centered therapy, exposure therapy was considerably more effective in reducing symptoms of PTSD in a sample of female veterans. The most developed model of exposure therapy is Prolonged Exposure (PE; Foa, Hembree, & Rothbaum, 2007), which consists of repeated imaginal exposure to a traumatic memory and in-vivo exposure to avoided current situations. The model contains lesser elements of psychoeducation about PTSD symptoms, rationale for treatment, and breathing retraining (Foa, Hembree, & Rothbaum, 2007).

The vast majority of PE efficacy trials have examined the protocol provided in an individual format. However, due to practical considerations such as cost, therapist time, and therapist-to-client ratios, most Veterans Administration (VA) outpatient programs offer PTSD treatments in a group format (Garrick, 2000). There is a paucity of research investigating the effectiveness of group PTSD treatments in general, and group exposure therapy in particular. The only systematic examination of PE delivered in a group format (Schnurr, Friedman, Foy, Shea, Hsieh, Lavori, et al., 2003) found no differential improvement in PTSD symptoms compared to a present-centered treatment approach in a sample of male Vietnam combat veterans. The active treatment group included only 2-3 in-session exposures to traumas and the

exposure component was embedded in a group with other treatment interventions including psychoeducation, cognitive restructuring, relapse prevention, and coping skills training over 30 sessions. The few in-session exposures and the group structure made it difficult to isolate the effectiveness of the exposure portion of treatment. Thus, while this study provided a necessary first step in systematically examining the effectiveness of a group prolonged exposure protocol, further examination of group exposure therapy is necessary. The aim of the present study was to examine the effectiveness of group exposure therapy in an applied setting when the exposure component is separated from other protocol treatments by groups, within a larger treatment protocol (Castillo, 2004).

Method

Participants

The sample consisted of 43 of 51 women who elected exposure therapy group within a larger sample of 230 women evaluated for PTSD treatment in the Women's Trauma Clinic (WTC) at the New Mexico VA Health Care System (NMVAHCS) between 1995 and 2003. The sample included 35 female veterans (81.4%) and 8 civilian women (18.6%; spouses of eligible male veterans). The subjects were diagnosed with current and/or lifetime PTSD due to childhood (n = 12, 27.9%), adult (n = 9, 20.9%), or both childhood and adulthood traumas (n = 22, 51.2%). Eighty-one percent reported more than one trauma, with 67% sexual, 3% other, including combat, and 30% a combination (sexual with other) of traumas. The average age was 43.7 (SD = 8.7). Thirty-three percent (n = 14) were married, 30% (n = 13) divorced, and 37% (n = 16) never married.

Measures

Entry Assessment. Assessment for the WTC program consisted of an initial semi-structured interview, computerized psychological tests, and the Clinician Administered PTSD Scale (CAPS; Blake, Weathers, Nagy, Kaloupek, Klauminzer, Charney, & Keane, 1990). The

17-symptom portion of the CAPS assessed for frequency and intensity of PTSD symptoms within the past month and lifetime. Other entry measures included the Minnesota Multiphasic Personality Inventory-2 (MMPI2; Butcher, 1989) and the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

Outcome measure. The Post-traumatic Stress Disorder Checklist (PCL; Weathers Litz, Herman, Huska, & Keane, 1993) was administered prior to each exposure group session. The instrument is a 17-item self-report measure of PTSD symptoms in response to a traumatic life event on a 5-point Likert scale. The reliability and validity of the PCL has been demonstrated in several studies (Ruggiero, Del Ben, Scotti, & Rabalais, 2003; Weathers et al., 1993).

Procedure

Each six-session exposure treatment group consisted of three female patients and two female co-facilitators. Attendance in the exposure group was optional, and other groups consisted of protocol-specific group interventions, such as cognitive restructuring (Resick & Schnicke, 1993), assertiveness/relaxation/nightmare therapies, and sexual functioning (see Castillo, 2004). Twelve women received exposure group prior to other structured treatments and 31 received the exposure group after other treatments. The exposure therapy group utilized modified exposure techniques by Keane, Foa, and Resick, where the worst trauma was identified as the index trauma (Foa, et al., 2007), written at home by the patient, read aloud in session (Resick & Schnicke, 1993), and in-session guided imaginal exposure or flooding conducted in each session (Keane, Fairbank, Caddell, & Zimering, 1989). The trauma was re-written for each exposure session and the process was repeated weekly for a total of four in-session imaginal exposures. Within each 90-minute group session, 30 minutes was allotted with each patient for trauma reading, exposure, and processing. After the patient completed the third in-session exposure, she was instructed to read the written trauma account daily at home for two weeks to continue desensitization (Resick & Schnicke, 1992).

Results

Descriptive Data

Select scales of entry assessment psychological testing and attendance data are shown in Table 1. The subjects had higher lifetime than current PTSD based on the CAPS; showed peaks on the F, 2, 8, PK, and PS scales of the MMPI-2; and a mean BDI score in the severely depressed range. Subjects with incomplete entry assessment data, CAPS (n = 17) and MMPI2/BDI (n = 9) were compared to subjects with entry data on baseline PCL scores using t-tests and no significant differences were found.

Outcome Analyses on PCL

Paired t-tests computed for pre- and post-PCL scores were significant for overall PTSD (Mpre = 3.43, SD = 0.78; Mpost = 3.11, SD = 0.97; p = .008) and within the two symptom categories of reexperiencing (Mpre = 3.42, SD = 0.94; Mpost = 3.08, SD = 1.11; p = .05) and avoidance/numbing (Mpre = 3.44, SD = 0.96; Mpost = 2.90, SD = 1.00; p = .0004). While effect size analyses typically require comparison of groups, the baseline standard deviation was used to compare means resulting in an effect size equal to -.47 for the total PTSD score (Becker, last accessed 5/30/08). An ANOVA was computed on PCL scores to compare order effects (exposure first versus last) with order and pre/post as predictor variables. No significant interaction was found, suggesting order of exposure treatment did not have an effect on treatment differences (pre/post).

A quadratic regression was computed on mean PCL totals across the six sessions within subjects and the quadratic effect was found significant (p = .003; Figure 1). In order to assure generalizability of results, the 8 subjects eliminated from the outcome analyses due minimal attendance data were compared to the 43 (total of 51 in exposure treatment) who completed treatment on baseline PCL scores and no significant differences were found using a logistic regression.

Discussion

The aim of the present study was to provide preliminary data on the feasibility and effectiveness of exposure therapy in a group setting among a sample of female veterans. Overall PTSD symptoms decreased from pre to post-therapy with group exposure therapy regardless of previous therapeutic interventions. This is particularly notable as the cognitive therapy module (Resick & Schnicke, 1992) has been shown to have similar effect sizes as PE (Rothbaum, Meadows, Resick, & Foy, 2000). The temporary increase followed by a decrease in PTSD symptoms also replicated past exposure therapy research.

Beyond the change on global PTSD symptom severity, it is important to note that the overall PTSD symptom reductions were driven by reductions in reexperiencing as well as avoidance/numbing symptoms. This finding is especially notable, as these symptom subsets are considered to be hallmark symptoms of PTSD (e.g. Foa, Riggs, Dancu, & Rothbaum, 1993). Moreover, current theory and empirical work indicate that emotional and behavioral avoidance is a key factor in the maintenance of the disorder (Foa, et al., 2007). Similarly, previous studies have shown that emotional numbing predicts the maintenance of PTSD over time (Feeny, Zoellner, Fitzgibbons, & Foa, 2000). Thus, the significant reduction in reexperiencing and avoidance/numbing clusters of PTSD symptoms further testifies to the utility of group exposure therapy.

Although the current results are interesting and suggest future research endeavors, it is important to note the methodological limitations, which consist of lack of randomization, reliance on a single self-report outcome measures, and the lack of follow up data. As such, future research would benefit from the inclusion of a control group, as well as the use of semi-structured interviews for outcome analyses. Finally, it would be clinically useful to examine the lasting effects of the treatment results over time, perhaps the standard three to six months after treatment.

Despite limitations, the current study provides encouraging preliminary results for the feasibility and effectiveness of exposure delivered in a group format. In turn, these results set the stage for larger-scale, future studies that improve on the methodology of the current work. This line of future research will ultimately lead to bridging the gap between treatment need and therapist supply by allowing the delivery of effective and efficacious treatments to higher numbers of patients experiencing PTSD symptoms.

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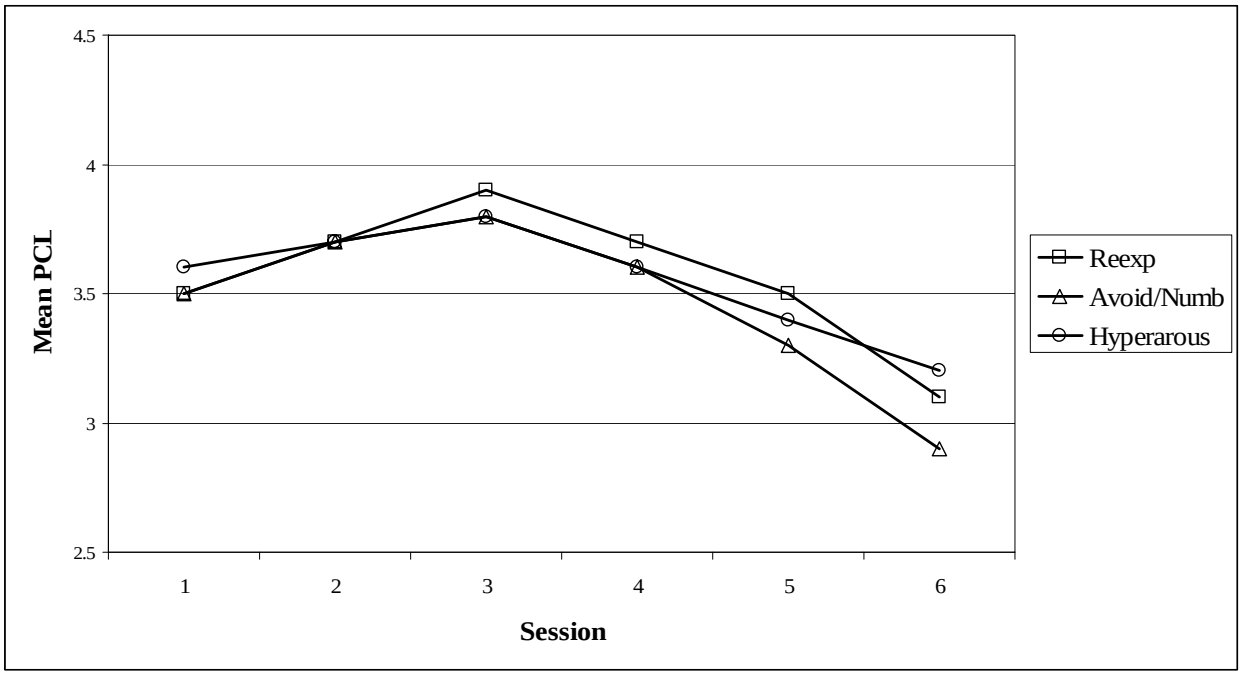
Table 1. Means and Standard Deviations for Entry Assessment and Attendance Data.

	Frequency		**Intensity**	
CAPS (*n* = 26)	*M*	*SD*	*M*	*SD*
Current	33.5	10.3	33.6	11.6
Lifetime	53.4	9.3	52.7	9.7
MMPI2 (*n* = 34)	*M*	*SD*	**Completed PCL**	
F	81.2	19.3	# of Sessions	*n* (%)
2 (Depression)	80.1	11.4	3	1 (2.3)
8 (Schizophrenia)	81.4	12.8	4	2 (4.7)
PK (Keane PTSD)	77.7	13.4	5	7 (16.3)
PS (Schlenger PTSD)	78.2	12.4	6	33 (76.7)
BDI (*n* = 34)	22.9	10.9		

Note: CAPS = Clinician Administered PTSD Scale; MMPI2 = Minnesota Mulitphasic Personality Inventory-2; BDI = Beck Depression Inventory; PCL = PTSD Symptom Checklist.

Figure Caption

Figure 1. Mean PCL scores for three symptom categories across six group exposure sessions.



Note. PCL = PTSD Symptom Checklist; Reexp = Reexperiencing symptoms; Avoid/Numb = Avoidance and Numbing symptoms; Hyperarous = Hyperarousal symptoms.